DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

95110d

One Montvale Avenue
Stoneham, Massachusetts 02180
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WARNING LETTER

NWE-03-05W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 22, 2004

Olivia Ho Cheng, President and CEO
Aurora Imaging Technology, Inc.
39 High Street
North Andover, Massachusetts 01845

Dear Ms. Cheng:

During an inspection of your establishment located in North Andover, Massachusetts, on September 13, 14, 15, 16 and 23, 2004, an investigator from the U.S. Food and Drug Administration (FDA) determined that your firm manufactures the Aurora® Dedicated Breast MRI System. This product is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

The inspection revealed your medical device is adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21 Code of Federal Regulations (21 CFR), Part 820 as follows:

1. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system (21 CFR 820.22). For example, your Internal Quality Audits procedure, 10-00004 requires annual quality audits be conducted. Of the [redacted] quality subsystems identified by your firm, only 3 have been audited within the past 18 months.

2. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions (CAPA) and to document all activities as required by 21 CFR 820.100(a) and (b). For example, you could not provide the CAPA Request

forms and CAPA logs required by section 6.0 of Procedure 28-00011, Rev. C, dated 12/19/00.

3. Your firm failed to control product that does not conform to specified requirements in that you failed to follow your Manufacturing Variance SOP, 28-00048, Rev. D, dated 12/19/00 (21 CFR 820.90). For example, DHR's for two of the [redacted] units manufactured since May 2002 showed data outside the tolerance limits and the Manufacturing Variance SOP was not followed.

4. Management with executive responsibility has not ensured an adequate and effective quality system has been fully implemented and maintained at all levels of the organization (21 CFR 820.20). Specifically:
   a. No procedures for management reviews have been established to ensure that the quality system satisfies the requirements of the Quality System regulation.
   b. The Quality Policy has not been implemented.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with each applicable requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge your response, dated October 14, 2004, to the FDA-483 List of Inspectional Observations. Your response fails to demonstrate to us your recognition of the seriousness of your quality system failures. We find your response inadequate for a number of reasons, including the following:

FDA-483 Observation #1b: You admit that the Management Review Procedure has not been implemented. Although you then state that the Management Review of the Quality System has been primarily addressed via the CAPA process, the CAPA process has not been implemented, as you admit in response to FDA-483 Observation # 5. In any event, a CAPA process can not adequately handle the functions of a Management Review Procedure. You also state the new Management Review SOP is scheduled for release 2 weeks after the CAPA SOP's and QA Policy Manual's releases, which are scheduled to occur in 4 - 6 weeks. Your response does not address the fact that FDA-483 observations #2, #3, and #5 are uncorrected observations from the previous inspection of May

2002. Given the length of time that has elapsed since the previous commitment to correct these observations, without adequate explanation of why additional time is necessary and how you are going to ensure against further quality problems in the interim, your planned implementation target is too remote.

FDA-483 Observation #2: You admit the Quality Policy Manual has not been released. Although you then state that you are addressing the requirements of 21 CFR 820.20, your response does not indicate how the requirements are being met. You also state your QA Policy Manual is scheduled to be released in 4 - 6 weeks. For the reasons provided above, your planned implementation target is too remote.

FDA-483 Observation #3: Although you admit very few of the [redacted] subsystems have been audited within the past 18 months, you do not provide a timetable to conduct the required internal audits.

FDA-483 Observation #4: You state the DHR inaccuracies were caused by new Manufacturing and Manufacturing Support personnel with no prior manufacturing experience. Although you then state that all employees have received additional O.J.T., you do not provide how you implemented, verified and documented this training. It is not clear if your personnel retested the two (2) units that contained data outside of the tolerances that you released, and no scientific rationale has been provided to show how these failing units meet "design release criteria" and "do not jeopardize patient safety." Furthermore, since you admit that these employees did not have prior manufacturing experience, all products manufactured and tested by these employees are suspect and should be retested.

FDA-483 Observation #5: You admit the CAPA system has not been implemented as specified in your CAPA Procedure 28-00011 Rev C. Although you then state that the new CAPA procedure has been in practice, but not formally released, the use of unapproved and informal procedures poses serious problems with your quality system. You also state that the new CAPA SOP is being developed and scheduled for release in 4 - 6 weeks. For the reasons provided above, your planned implementation target is too remote.

Please notify this office in writing within fifteen (15) working days from the date you received this letter of the additional steps you have taken, or will take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be directed to Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Sincerely,

Gail T. Costello
District Director
New England District Office